

REMARKS/ARGUMENTS

General Remarks

All of the presently pending method claims expressly require that the device is used *from a position proximal of the target tissue*. Thus, the device operates in a manner distinct from a syringe in which the device is inserted into the tissue that is to be clarified. Similarly, the optical portion *delivers the light from the proximal position* in a manner such that the light will pass through an opening (or topmost layer) into or below an area of clarified tissue.

Also, with respect to Chan et al., applicant points out that *Chan et al. use deep infrared light* in their devices and methods (e.g., column 6, lines 35 et seq.: any wavelength within the continuous range of 0.9-20 microns [*i.e.*, 900 nm-2000 nm]), while the present subject matter is drawn to visible light. Such difference is not trivial as all of the claimed methods are drawn to tissue clarification (*light scattering is a function of the wavelength*) for visible light delivery.

35 USC § 112

Claims 37-70 were previously rejected under 35 USC § 112, first paragraph, as lacking enabling description for various elements. *Claims 37-70 are canceled and the rejection is therefore moot*. The applicant points out that all new added claims are apparatus claims (as opposed to method of use claims), in which the apparatus includes *components with known configuration and use parameters*.

If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, then 35 U.S.C. 112 is satisfied. (In re Johnson, 282 F.2d 370, 373, 127 USPQ 216, 219 (CCPA 1960); In re Hitchings, 342 F.2d 80, 87, 144 USPQ 637, 643 (CCPA 1965). See also In re Brana, 51 F.2d 1560, 1566, 34 USPQ2d 1437, 1441 (Fed. Cir. 1993)).

The specification points out both, connotations how to use as well as the fact that the art recognizes standard modes of administration are known and contemplated (see e.g., Description of Figure 6). Thus, as all of the recited devices are well within the scope of a person of ordinary skill in the art, and new claims 71-90 should not be deemed as lacking enabling support.

35 USC § 102

Claims 37-56, 62, and 69 were previously rejected under 35 USC § 102 as being anticipated by Martinez (U.S. Pat. No. 4,222,375). *Claims 70-85 were canceled and the Examiner's rejection is therefore moot.* Nevertheless, Martinez is addressed below to point out why the new claims are not anticipated by these references.

Among other elements, all of the new claims expressly require that the light emitted by the optical portion "...*passes through the conjunctiva or opening to an area within or below the area of clarified sclera...*" (claims 71-77), "...*passes through the permeability barrier to an area within or below the area of clarified tissue...*" (claims 78-85), or "...*passes through the stratum corneum or opening to an area within or below the area of clarified tissue...*" (claims 86-90). The claims further expressly require that "...the apparatus is configured such that the opening is formed, the clarifying agent is delivered, and the light is emitted when the apparatus is in a *position proximal to the sclera...*" (claims 71-77), "...the apparatus is configured such that the clarifying agent is driven through the permeability barrier and the light is emitted to the area when the apparatus is in a *position proximal to the tissue disposed below the permeability barrier...*" (claims 78-85), and "...the apparatus is configured such that the opening is formed, the clarifying agent is delivered, and the light is emitted when the apparatus is in a *position proximal to the tissue disposed below the stratum corneum...*" (claims 86-90).

These elements are clearly neither taught nor suggested by Martinez as his device needs invasive insertion into the target tissue. Indeed, modification of Martinez' device to create an apparatus according to the presently claimed subject matter would render Martinez' device inoperable for its intended purpose. Therefore, the new pending claims are not only novel in light of Martinez, but also non-obvious.

35 USC § 103

Claims 37-70 were previously rejected under 35 USC § 103 as being obvious in various combinations over Chan (U.S. Pat. No. 6,275,726), Martinez (U.S. Pat. No. 4,222,375), Edwards, (U.S. Pat. No. 5,833,647), and Weaver (U.S. Pat. No. 5,019,034). Again, *claims 37-70 were canceled and the rejection is therefore moot.* Nevertheless, the references are addressed

below to point out why the new claims are not obvious over these references.

With respect to Martinez, the same arguments as provided above apply. It should be noted that ***none of Chan, Weaver, and Edwards can cure these defects*** as obviousness can only be properly be established when, each and every element is taught, suggested, and motivated by the references. This is clearly not the case.

With respect to Chan, the applicant points out that Chan teaches chemical abrasion, mechanical debridement, etc. to remove the stratum corneum, which at least ***teaches away***, if not even against the new claims as such techniques require dedicated and separate devices. Moreover, Chan (and for that matter none of the other references) teach formation of an opening in a conjunctiva. A ***conjunctiva is clearly inconsistent with a stratum corneum***. It should be pointed out that the differences between a conjunctiva and the stratum corneum are substantial, and that the conjunctiva is not just an obvious variant of the stratum corneum and *vice versa*. Among other things, the stratum corneum comprises optically dispersive, dead cells while the conjunctiva comprises living, optically clear cells. Finally, Chan also fails to teach application of a clarifying agent to enhance optical transparency of the sclera. Once more, a ***sclera*** (i.e., the 'white in an eye') ***is entirely inconsistent with a dermal tissue underlying the stratum corneum*** as a person of ordinary skill in the art would not be motivated to clarify a sclera where access can be obtained though the lens. These defects are not remedied by the cited references.

Weaver is concerned with ***electroporative transdermal transport of drugs*** into skin or other subdermal compartments. No optical portion is taught or suggested. Indeed, delivery of a drug across the skin as taught by Weaver requires no optical instrument at all. Still further, Weaver is entirely silent on the issue of ophthalmological methods. Clearly, Weaver fails to teach or suggest almost all of the elements in the presently pending claims.


Edwards teaches enhancing mass transfer through a hydrogen or lipogel to skin. Thus, any transport taught by Edwards does not focus on delivery of a molecule to a covered biological tissue, but instead deals with mass transport through a non-skin component (i.e., hydrogel or lipogel). It is unclear to the applicant how Edwards was applied to the previously pending and now canceled claims.

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In view of the present amendments and arguments, the applicant believes that all claims are now in condition for allowance. Therefore, the applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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